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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,986	PAUL, LEONARD	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-30 are pending and are therefore examined herein on the merits for patentability. No claim is allowed at this time.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 7 and 11-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,830,557. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a medical delivery

system comprising a medicinal composition within a container for dispensing the therapeutic agent, wherein the medical composition comprises a surfactant, a therapeutic agent, and water. Although the scope of the copending claims are not identical, many of the surfactants are the same (i.e. ethoxylated aliphatic phenolics such as nonoxynol-9 and octoxynol-9, and vegetable oil based soaps such as glycerine), and many of the therapeutic agents are the same (i.e. silver nitrate solutions and silver nanocrystals). Also, the containers comprising the medicinal compositions are overlapping in scope in that they comprise either a finger-actuated foam producing valve bearing or squeeze bottle foam producing container. Furthermore, both sets of claims are drawn to the containers comprising an elongated tube portion formed from flexible material with at least one aperture formed along the distal end and a closure means comprising caps or finger-operated dispensing valves. Therefore, the scopes of the copending claims are overlapping are thus they are obvious variants of one another.

2. Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,555,508. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a medical delivery system comprising a medicinal composition within a container for dispensing the therapeutic agent, wherein the medical composition comprises a surfactant, a therapeutic agent, and water. Although the scope of the copending claims are not identical, many of the surfactants are the same (i.e. polysorbate 20, cocoamide DEA, polysorbate 60, polysorbate 80,

ammonium or alkaline salts of sulfated aliphatic alcohols, ammonium or alkaline salts of sulfated aliphatic ethoxylated alcohols, cocoamido derivatives, and ethoxylated aliphatic phenolics), and many of the therapeutic agents are the same (i.e. silver nitrate solutions). Also, the containers comprising the medicinal compositions are overlapping in scope in that they comprise either a finger-actuated foam producing valve bearing or squeeze bottle foam producing container. Therefore, the scopes of the copending claims are overlapping are thus they are obvious variants of one another.

Claim Objections

1. Claim 6 is objected to because of the following informalities: the 4th line of the instant claim recites, "sodium lauryl surfaocetate". However, it is believed Applicant intended, "sodium lauryl sulfoacetate", as recited in instant claims 1 and 4. Appropriate correction is required.

2. Claim 13 is objected to because of the following informalities: the 1st line of the instant claim recites, "The delivery system *and* defined in Claim 11". However, it is believed Applicant intended either "The delivery system *as* defined in Claim 11" or "The delivery system defined in Claim 11", the latter of which follows the claim language of the other dependent claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claim 1 recites the limitation "the foam mousse" in the 2nd line of component "B". There is insufficient antecedent basis for this limitation in the claim.

2. Claims 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claims 27-30 recite the limitation "The medicinal delivery system" in the preamble of the claims. There is insufficient antecedent basis for this limitation in the claim. Claims 27-30 are dependent from claim 26, which is drawn to a composition, and does not refer to a medicinal delivery system.

3. Claims 1, 19, 22 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claims 1, 19, 22 and 26 recite, "silver nitrate solutions, silver nanocrystals, colloidal silver, colloidal silver solutions, and ***equivalents thereof***." However, it is not clear what Applicants intend by equivalents of silver nitrate solutions, silver nanocrystals, colloidal silver, and colloidal silver solutions.

It is not clear if the therapeutic agent needs to be structurally equivalent, exhibit equivalent antibacterial activity, exhibit equivalent antiviral activity, exhibit equivalent antimicrobial activity, exhibit equivalent physical properties, etc. Therefore, the metes and bounds of the instant claims are not clearly defined. For the purposes of examination, the examiner is construing the claims to intend compounds which exhibit equivalent antibacterial/antiviral/antimicrobial efficacy. However, it is still unclear whether these compounds need contain a silver atom, or if any compound exhibiting antibacterial/antiviral/antimicrobial efficacy that is equivalent to the above mentioned silver-containing compounds will be sufficient. The latter interpretation is a much more broad interpretation that includes a plethora of antibacterial, antiviral and/or antimicrobial compounds applied in any concentration that renders equivalent efficacy as the said silver-containing compounds.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1, 22 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cocoamide DEA (a.k.a. cocamide DEA), does not reasonably provide enablement for all cocoamido derivatives. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

nearly connected, to make and use the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the nature of the invention
2) the state of the prior art
3) the relative skill of those in the art
4) the predictability of the art
5) the breadth of the claims
6) the amount of direction or guidance provided
7) the presence or absence of working examples
8) the quantity of experimentation necessary

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

The nature of the invention

The claimed invention relates to a foam producing composition comprising a surfactant, therapeutic agent and water, as well as a container comprising said composition.

The state of the prior art

At the time of the instant invention surfactant compounds for foam compositions were well known, including cocoamide DEA.

The relative skill of those in the art

A person of ordinary skill in the art at the time of the instant invention would have reasonably known that cocoamide DEA was a surfactant suitable for use in foam producing compositions.

The predictability of the art

However, it is not possible to predict the physical properties of all derivatives of a compound, regardless of the properties of the parent compound.

The breadth of the claims

The claims are very broad because the recitation of cocoamido derivatives encompasses a plethora of compounds including any number of structural permutations to cocoamide.

The amount of direction or guidance provided

The instant specification does not provide any direction or guidance with respect to ascertaining the meaning of cocoamido derivatives or to compounds that are encompassed by this genus.

The presence or absence of working examples

The specification merely provides an example wherein cocoamide DEA is used as a surfactant in a foam composition (Table XII). The specification does not provide other examples of cocoamido derivatives suitable for use as surfactants in the instant invention.

The quantity of experimentation necessary

It would require undue experimentation for a person of ordinary skill in the art at the time of the instant invention to determine the properties of all cocoamido derivatives in order to determine if they would be suitable for use as surfactants in the instant invention.

Therefore, for the aforementioned reasons, the Applicant is enabled for cocoamide DEA (a.k.a. cocamide DEA), but is not reasonably enabled for all cocoamido derivatives.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 11-12, 14-15 and 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Great Britain Patent No. 1,372,721 (hereinafter James).

James discloses a container of antiseptic for the treatment of burns and scalds by topical application, comprising at least one surfactant, a topically acceptable antiseptic active agent, and water, wherein the container comprises an outlet and valve

means operable to allow discharge of the contents in the form of a foam (page 1, lines 26-37), which effectively controls *Pseudomonas aeruginosa* (page 5, lines 14-16). Also, James discloses a surfactant composition comprising cocodimethylamine-N-oxide (page 3, lines 92-96). James further discloses the container comprising silver nitrate solutions (page 2, lines 95-96 and 113-115; page 4, lines 87-90, 108-110 and 119-120; and claim 14) or silver salt preferably in conjunction with a protective colloid (page 2, lines 68-71).

It is noted that the recitation of the intended use "for ease of insertion into an orifice communicating with a cavity of the human body" and "for further assisting in providing ease of insertion and positioning of the tube member in the desired orifice", as recited in instant claims 11 and 15 respectively, has not been given patentable weight to distinguish over the container disclosed by James because the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since James discloses a container that meets the physical limitations of the instant claims (i.e. valve assembly, dispensing nozzle of plastics material, metal cap secured to the body, and tapered delivery nozzle) (page 3, lines 33-78; and Figures 1 and 2), it would be capable of performing the intended use, as claimed.

2. Claims 1, 22-24, 26 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2002/0137641 (hereinafter Paul '641).

Paul '641 disclose a liquid foaming soap composition comprising a mixture of surfactants (i.e. polysorbate 20, cocoamide DEA, polysorbate 60, polysorbate 80, ammonium or alkaline salts of sulfated aliphatic alcohols, ammonium or alkaline salts of sulfated aliphatic ethoxylated alcohols, cocoamido derivatives and ethoxylated aliphatic phenolics) in combination with water, and further comprising at least one therapeutic agent (i.e. silver nitrate solutions) (claims 1-6). Paul '641 further disclose the composition being dispensed from a container selected from the group consisting of finger actuated foam producing valve bearing containers and squeeze bottle foam producing containers, wherein the squeeze bottle container further comprises an elongated delivery nozzle formed thereon for enabling insertion thereof into elongated cavities formed in the human body (claims 7-8).

Also, Paul '641 disclose a process for achieving a multi-purpose improved liquid foaming soap delivery system for medicinal benefit comprising forming a foam composition as described above, placing the foam composition into a container described above, and applying the foam mousse to a desired site, such as the cavity of the human body (claims 22-23).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome

either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/17595 (hereinafter Gilchrist et al.).

Applicant claims:

Applicants claim a composition comprising 0.1 to 60 wt.% surfactant (i.e. polysorbate 20, 60, and 80, and vegetable oil based soaps), an effective amount of a therapeutic agent (i.e. silver nitrate solutions), and water forming the balance.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Gilchrist et al. teach a physiologically acceptable foamable formulation comprising an active ingredient and a foamable, physiologically acceptable carrier, and optionally comprising a foaming agent (i.e. surfactant) (page 2, lines 7-17).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Gilchrist et al. do not explicitly teach the composition comprising an active agent selected from silver nitrate solutions, silver nanocrystals, colloidal silver and colloidal silver solutions, in combination with a surfactant. However, Gilchrist et al. teach the active ingredient may be selected from silver nitrate or other silver compounds, which are effective against gram negative species (page 9, lines 5-15; and page 11, lines 15-17), and the foaming agent may be selected from cationic, non-ionic, or anionic surfactants, such as lecithin, soaps, and Tween (a.k.a. polysorbate) (page 8, line 31 through page 9, line 1; and Examples 3-5 and 7-12). Also, Gilchrist et al. teach all of the compositions comprising water (Examples 1-12).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use silver nitrate in the composition of Gilchrist et al. further comprising a surfactant, such as lecithin, soaps or Tween. One of ordinary skill in the art at the time of the instant invention would have been motivated to use silver nitrate

solutions because Gilchrist et al. teach silver compounds as suitable active agents for use in their invention, as well as being effective against gram negative species.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilchrist et al. in view of U.S. Patent No. 5,614,568 (hereinafter Mawatari et al.).

Applicant claims:

Applicants claim a composition comprising colloidal silver, a surfactant, and the balance being water, wherein the colloidal silver is about 10 to 32 ppm in water and the colloidal silver in water solution is about 40 to 99.8 wt.% of the entire composition.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Gilchrist et al. teach a physiologically acceptable foamable formulation comprising an active ingredient (i.e. silver nitrate) and a foamable, physiologically acceptable carrier, and optionally comprising a foaming agent (i.e. surfactant), as discussed above. Gilchrist et al. also teaches the active ingredient is present in an amount of about 1 wt.% and water is present in an amount of about 80 wt.% (Examples 1-12).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Gilchrist et al. do not teach the active ingredient to comprise colloidal silver. However, Mawatari et al. teach silver nitrate and colloidal silver to be functionally equivalent antibacterial agents (column 4, lines 62-63; and column 5, lines 10-11, 13, 24-25, 28 and 31-32). Mawatari et al. further teach that aqueous colloidal silver has a great antibacterial activity and is little harmful to human body (column 5, lines 43-47). Mawatari et al. further teach the colloidal silver has a silver content of 0.02 to 1 wt.% and a particle size of 50 mμ or less, and more preferably a silver content of 0.05 to 0.2 wt.% and a particle size of 10 mμ or less (column 5, lines 58-64).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use colloidal silver in the foam composition of Gilchrist et al. because colloidal silver is functionally equivalent to silver nitrate, as reasonably taught by Mawatari et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

3. Claims 2-3, 7, 25, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul '641 in view of Rodionov et al., Pharm. Chem. J., 1992 (hereinafter Rodionov et al.).

Applicant claims:

Applicants claim a medicinal delivery system comprising a surfactant, a therapeutic agent, and water in a container, wherein the therapeutic agent is colloidal silver in solution with about 10 to 32 ppm or silver nanocrystal powder. Applicants also claim a method for delivering the above composition.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Paul '641 teaches a liquid foaming soap composition comprising a mixture of surfactants in combination with water, and further comprising at least one therapeutic agent, as well as a process for achieving a multi-purpose improved liquid foaming soap delivery system for medicinal benefit comprising forming a foam from said liquid foaming soap composition, as discussed in detail above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Paul '641 does not teach the therapeutic agent to comprise colloidal silver or silver nanocrystal powder. However, the bactericidal and antiviral properties of colloidal silver have been widely known for a long time, as evidenced by Rodionov et al. (page 778, first paragraph). Rodionov et al. further teach colloidal silver with a particle size of 1.9 nm in water at about 35 ppm having antiviral properties (0.05% protargol in solution

with protargol comprising 7 wt.% silver content) (page 778, lines 5-6 after "Experimental", and page 779, lines 4-5 and 15-16 excluding the text of Table 1 and not counting spaces).

It is noted that the amount of silver present in the solution of protargol as taught by Rodionov et al. comprises about 35 ppm, whereas the instant claims are directed a silver content of between about 10 to about 32 ppm. However, 35 ppm silver would reasonably have substantially the same physical and chemical properties to 32 ppm silver in solution, and therefore, in the absence of evidence to the contrary, about 32 ppm silver would have been obvious in light of the teaching of about 35 ppm silver.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use approximately 35 ppm colloidal silver with a particle size of 1.9 nm, as taught by Rodionov et al., in the place of silver nitrate in the liquid foaming soap composition of Paul '641, because colloidal silver has been known for a long time to possess antibacterial and antiviral properties. One of ordinary skill in the art at the time of the instant would have had a reasonable expectation of success in using colloidal silver because it is readily known to have antibacterial and antiviral properties, as evidenced by Rodionov et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to

one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paul '641 in view of Rodionov et al., as applied to claims 2-3, 7, 25, 27 and 29, and further in view of U.S. Patent No. 5,254,334 (hereinafter Ramirez et al.).

Applicant claims:

Applicants claim a medicinal delivery system according to claim 3 wherein the surfactant is 0.1 to 30 wt.% of sodium lauryl sulfoacetate, sodium lauroyl sarcosinate or vegetable oil based soap.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Paul '641 teaches a liquid foaming soap composition comprising a mixture of surfactants in combination with water, and further comprising at least one therapeutic agent, as well as a process for achieving a multi-purpose improved liquid foaming soap delivery system for medicinal benefit comprising forming a foam from said liquid foaming soap composition, as discussed in detail above.

Rodionov et al. teach colloidal silver with a particle size of 1.9 nm in water at about 35 ppm having antiviral properties.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Paul '641 and Rodionov et al. do not teach the surfactants to comprise sodium lauryl sulfoacetate, sodium lauroyl sarcosinate or vegetable oil based soaps. However, Ramirez et al. teach foam compositions for topical administration (column 1, lines 7-32), wherein the foam composition comprises glycerine, sodium cocoyl isethionate, sodium lauryl sulfate, emollients, foam boosters, and additives (column 2, lines 32-68). Ramirez et al. also teach that sodium lauryl sulfoacetate and sarcosynates are foam boosters that enhance the foam produced when exposed to water during use (column 2, lines 51-58; and claims 6-8). Ramirez et al. further teach that additional active ingredients such as vitamin A, vitamin E, and antibacterial agents may be incorporated into their foam compositions (column 2, lines 59-68).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use sodium lauryl sulfoacetate or sarcosynates as foam boosters in the foam compositions of Paul '641, in order to enhance the foam produced when exposed to water during use, as reasonably taught by Ramirez et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to

one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

5. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul '641 in view of Rodionov et al. and Ramirez et al., as applied to claims 2-4, 7, 25, 27 and 29, and further in view of U.S. Patent No. 5,296,215 (hereinafter Burke et al.).

Applicant claims:

Applicants claim a medicinal delivery system according to claim 4, wherein the colloidal silver in water is 99 to 99.8 wt.% of the composition and the surfactant is sodium lauryl sulfoacetate or sodium lauroyl sarcosinate.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Paul '641, Rodionov et al., and Ramirez et al. teach a liquid foaming soap composition comprising a mixture of surfactants (i.e. sodium lauryl sulfoacetate and sarcosynates) in combination with water, and further comprising at least one therapeutic agent (i.e. colloidal silver), as well as a process for achieving a multi-purpose improved liquid foaming soap delivery system for medicinal benefit comprising forming a foam from said liquid foaming soap composition, as discussed in detail above. Also, Paul '641 teaches a composition wherein the only components are the 5 to 70 wt.% surfactant, an effective amount of therapeutic agent and 40 to 95 wt.% water (Table I).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Paul '641, Rodionov et al., and Ramirez et al. do not teach the colloidal silver in water comprising 99 to 99.8 wt.% of the composition. However, Burke et al. teach that sodium lauryl sulfoacetate is incorporated into a foam composition at about 0.1 to 3 wt.%, preferably 0.3 to 1.5 wt.% (column 3, lines 16-19).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to only incorporate 0.3 to 1.5 wt.% of sodium lauryl sulfoacetate into composition of Paul '641, which also comprises a therapeutic agent and water. One of ordinary skill in the art would have been motivated to only use 0.3 to 1.5 wt.% sodium lauryl sulfoacetate, leaving 98.5 to 99.7 wt.% of the composition to be therapeutic agent in water, because Paul '641 teaches a composition comprising only those three ingredients and Burke et al. teach only 0.3 to 1.5 wt.% sodium lauryl sulfoacetate is necessary.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. Claims 7 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over James in view of U.S. Patent No. 5,454,886 (hereinafter Burrell et al.).

Applicant claims:

Applicants claim a medicinal delivery system defined in claim 1 as well as a foam producing composition defined in claim 26, wherein said therapeutic agent is about 0.05 to 1 wt.% silver nanocrystal powder.

Determination of the scope and content of the prior art

(MPEP 2141.01)

James teaches a container of antiseptic for the treatment of burns and scalds by topical application, comprising at least one surfactant (i.e. cocodimethylamine-N-oxide), a topically acceptable antiseptic active agent (i.e. silver nitrate), and water, wherein the container comprises an outlet and valve means operable to allow discharge of the contents in the form of a foam, which effectively controls *Pseudomonas aeruginosa*, as discussed in more detail above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

James does not teach the antiseptic active agent to comprise nanocrystalline silver powder. However, Burrell et al. teach that the antimicrobial effects of metallic silver ions are well known, wherein silver has unusually good bioactivity at low concentrations and is used in modern medical practices to prevent and treat microbial infections (column 1, lines 28-39). Burrell et al. also teach that silver nitrate releases silver ions instantaneously in contact with water, whereas antimicrobial metal powders,

which are biocompatible and non-toxic, release atoms, ions, molecules or clusters of the antimicrobial metal at a sufficient rate and concentration, over a sufficient time period to provide a useful antimicrobial effect (column 5, lines 40-48 and 58-64). Furthermore, Burrell et al. teach that nanocrystalline silver powder (crystal size about 30 nm) has a zone of inhibition of 5 mm (column 16, lines 61-63), which indicates a highly useful antimicrobial effect (column 6, lines 7-8). Burrell et al. also teach *Pseudomonas aeruginosa* as considerably sensitive to silver compounds (column 19, line 49).

It is noted that Burrell et al. do not teach the percentage of nanocrystalline silver powder required for the desired antimicrobial efficacy. However, Burrell et al. teach that silver is perhaps the best known antimicrobial metallic ion due to its unusually good bioactivity at low concentrations, a phenomena referred to as oligodynamic action (column 1, lines 34-37). The examiner respectfully points out the following from MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Therefore,

it would have been *prima facie* obvious for a person of ordinary skill in the art at the time of the instant invention to determine the amount of nanocrystalline silver powder, as taught by Burrell et al., required to possess the necessary antimicrobial activity.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use nanocrystalline silver powder in the antiseptic formulation of James, because Burrell et al. teach that nanocrystalline silver powder is biocompatible and non-toxic, and has a highly useful antimicrobial effect against *Pseudomonas aeruginosa*.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

7. Claims 8-9, 28 and 30 rejected under 35 U.S.C. 103(a) as being unpatentable over James in view of Burrell et al., as applied to claims 1, 7, 11-12, 14-15, 22-26 and 29 above, further in view of Ramirez et al.

Applicant claims:

Applicants claim a medicinal delivery system according to claim 7, and a foam producing composition according to claim 26 or 28, wherein the surfactant is sodium lauryl sulfoacetate, sodium lauroyl sarcosinate, or vegetable oil based soap.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The combined teachings of James and Burrell et al. teach a container of antiseptic comprising at least one surfactant, a topically acceptable antiseptic active agent, such as nanocrystalline silver powder, and water, as discussed in more detail above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

James and Burrell et al. do not teach the surfactant to comprise sodium lauryl sulfoacetate, sodium lauroyl sarcosinate, or vegetable oil based soap. However, Ramirez et al. teach foam compositions for topical administration (column 1, lines 7-32), wherein the foam composition comprises glycerine, sodium cocoyl isethionate, sodium lauryl sulfate, emollients, foam boosters, and additives (column 2, lines 32-68). Ramirez et al. also teach that sodium lauryl sulfoacetate and sarcosynates are foam boosters that enhance the foam produced when exposed to water during use (column 2,

lines 51-58; and claims 6-8). Ramirez et al. further teach that additional active ingredients such as vitamin A, vitamin E, and antibacterial agents may be incorporated into their foam compositions (column 2, lines 59-68).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use the foam boosters sodium lauryl sulfoacetate or sarcosynates as surfactants in the foam producing compositions of James and Burrell et al. One of ordinary skill in the art at the time of the instant invention would have been motivated to use sodium lauryl sulfoacetate or sarcosynates as surfactants because Ramirez et al. teach said surfactants as foam boosters that enhance the foam produced when exposed to water during use.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over James in view of Burrell et al. and Ramirez et al., as applied to claims 1, 7-9, 11-12, 14-15, 22-26 and 28-30 above, further in view of after Burke et al.

Applicant claims:

Applicants claim a medicinal delivery system according to claim 9, wherein the additive is propylene glycol or denatured ethanol.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The combined teachings of James, Burrell et al. and Ramirez et al. teach a container of antiseptic comprising at least one surfactant, such as sodium lauryl sulfoacetate or sarcosynates, a topically acceptable antiseptic active agent, such as nanocrystalline silver powder, and water, as discussed in more detail above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

James, Burrell et al. and Ramirez et al. do not teach the additive to be propylene glycol or denatured alcohol. However, it is well known in the art at the time of the instant invention that humectants can be added to topical foam compositions to improve the feel on the skin. Burke et al. teach 10 to 40 wt.%, preferably 15 to 30 wt.% propylene glycol exemplifies humectants used in foam compositions (column 4, lines 50-58).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use 10 to 40 wt.%, preferably 15 to 30 wt.% propylene glycol in the foam composition of James, because propylene glycol is an exemplary humectant for foam compositions, as reasonably taught by Burke et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. Claims 13 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over James in view of U.S. Patent No. 4,531,659 (hereinafter Wright).

Applicant claims:

Applicants claim a medicinal delivery system comprising a composition of a surfactant, a pharmaceutical agent and water, and a container for dispensing said composition, wherein the container comprises a finger-actuated foam producing valve bearing or a squeeze bottle foam producing container and a flexible elongated tube portion.

Determination of the scope and content of the prior art

(MPEP 2141.01)

James teaches a container of antiseptic for the treatment of burns and scalds by topical application, comprising at least one surfactant, a topically acceptable antiseptic active agent and water, wherein the container comprises an outlet and valve means operable to allow discharge of the contents in the form of a foam, which effectively controls *Pseudomonas aeruginosa*, as discussed in more detail above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

James does not teach the container comprising an elongated flexible tube for ease of use and insertion into the human body. However, Wright teaches a foam-producing device (Figures 4 and 7) comprising a squeeze bottle 112 (column 3, lines 4-8), and an elongated flexible nozzle 130 (column 4, line 44) held in place by a cap 118 threaded to the squeeze bottle 112 (column 4, line 39), which facilitates insertion into body cavities, such as the vaginal cavity, to deposit medicinal foam (column 1, lines 63-65; column 2, lines 1-2; and column 5, lines 44-47).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use the foam-producing device of Wright for delivering the antiseptic composition of James to a desired site. One of ordinary skill in the art would

have been motivated to use the foam-producing device of Wright because its long flexible nozzle permits for easy insertion into cavities of the human body.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,965,500 (hereinafter Puvvada) in view of Friedman and Wolf, Clinic in Dermatology, 1996 (hereinafter Friedman et al.), Sheely, J. Amer. Oil Chem. Soc., 1935 (hereinafter Sheely), and Grier, Antiseptics and Disinfectants, 1983 (hereinafter Grier).

Applicant claims:

Applicants claim a composition comprising about 10 to 50 wt.% of a vegetable oil based soap, about 50 to 90 wt.% water, about 0.3 to 2 wt.% lanolin, and an effective amount of silver nanocrystals, silver nitrate solutions, colloidal silver, or colloidal silver solutions. Claim 20 further limits the vegetable oil to consist of palm kernel oil or coconut oil. Claim 21 further limits the silver to colloidal silver in water.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Puvvada teaches high foaming aqueous liquid compositions with level of oil/emollient equal to or in excess of level of surfactant (Abstract; column 1, lines 54-63;

and claim 1). Puvvada also teaches the oil/emollient comprising vegetable oils, such as coconut oil and kernel palm oil, animal fats, such as lanolin, or mixtures thereof, which is present from about 10-35 wt.%, preferably 10 to 30 wt.% (column 6, lines 13-18, 28-29 and 40-41). Also, Puvvada teaches water will comprise the balance of the composition, which is present in an amount greater than about 30 wt.%, preferably greater than about 40 wt.% of the composition (column 6, lines 57-59). Puvvada further teaches the compositions may comprise antimicrobials (column 7, line 7).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Puvvada does not explicitly teach the oil/emollient to comprise a combination of vegetable oils and lanolin. Nor does Puvvada explicitly teach the oil/emollient to be coconut oil or palm kernel oil. However, Puvvada does teach that vegetable oils are the preferred oil/emollient, with sunflower oil being the most preferred (column 6, line 36). Also, Friedman et al. teach that most toilet soap bars are made of a mixture of feedstocks derived from tallow fat and coconut oil, whereas the modern consumer trend created a demand for soaps based on the mixture of palm oil and coconut oil (page 8, 2nd column, 1st full paragraph). Freidman et al. further teaches that 05-5 wt.% humectants and moisturizers, such as glycerin and lanolin, are very important for skin "afterfeel" and for dermatological marketing claims (page 8, Table 1; and page 12, 2nd column, last paragraph).

Puvvada also does not teach the aqueous foaming composition comprising an antimicrobial to comprise silver nanocrystals, silver nitrate solutions, colloidal silver, or

colloidal silver solutions. However, Sheely teaches that silver compounds have been used in making antiseptic soaps as early as 1935, with the purpose of imparting disinfectant qualities to the soaps (page 220, 1st column, 1st paragraph, "Silver Compounds Used in Making Antiseptic Soaps"). Also, Grier teaches colloidal silver as an antimicrobial agent suitable for use in topically applied compositions (page 375, 1st column, lines 24-33; page 376, 2nd column, "Colloidal Silver Preparations"; page 377, 2nd column, "Colloidal Metallic Silver" and "Colloidal Silver Halides").

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use 10-35 wt.% vegetable oil, such as palm kernel oil or coconut oil, 0.5-5 wt.% animal fat, such as lanolin, and an effective amount of colloidal silver as the antimicrobial in the composition of Puvvada. One of ordinary skill in the art at the time of the instant invention would have been motivated to use vegetable oils, such as coconut oil or palm kernel oil, in combination with lanolin because Friedman et al. teaches that most toilet bars and most "back to nature" vegetable soaps are based on coconut oil, and lanolin is a moisturizer that is very important for skin "afterfeel" and for dermatological marketing claims. One of ordinary skill in the art at the time of the instant invention would have been motivated to use colloidal silver as the antimicrobial because silver compounds, such as colloidal silver, have been known for over 100 years to possess antiseptic properties and have been used topically for such purposes, as reasonably taught by Sheely and Grier.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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